



JAN 31 2008

Bruce E. Kramer
Sughrue Mion PLLC
2100 Pennsylvania Avenue, NW
Suite 800
Washington, DC 20037-3213

In re: Patent Term Extension
Application for
U.S. Patent No. 5,284,858

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,284,858, which claims the human drug product AMITIZA® (lubiprostone), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1252 days (3.4 years).

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1252 days (3.4 years).

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 23, 2007 (72 Fed. Reg. 36). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1890 - 0) + 307 \\ &= 1252 \text{ days (3.4 years)}\end{aligned}$$

Since the regulatory review period began January 28, 2000, after the patent issued (February 8, 1994), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,284,858
Granted:	February 8, 1994
Original Expiration Date ¹ :	February 8, 2011
Applicant:	Ryuzo Ueno <i>et al.</i>
Owner of Record:	Sucampo AG

¹Subject to the provisions of 35 U.S.C. § 41(b).

Title: Prostaglandins E and Anti Ulcers Containing Same
Product Trade Name: AMITIZA® (lubiprostone)
Term Extended: 1252 days (3.4 years)
Expiration Date of Extension: July 14, 2014

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7754
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7754.



Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

Re: AMITIZA® (lubiprostone)
FDA Docket No.: 2006E-0355